

Attorney Docket No.: **06244-0002 (CHM-0003)**
Inventors: **Hulkower et al.**
Serial No.: **10/775,780**
Filing Date: **February 10, 2004**
Page 7

REMARKS

Claims 1-136 were pending in this application and have been canceled by this preliminary amendment and replaced by new claims 137-153. No new matter has been added. Applicants are respectfully requesting reconsideration of the restriction requirement in view of this preliminary amendment and the following remarks.

The originally filed claims have been subjected to a Restriction Requirement under 35 U.S.C. §121 by the Examiner in this case. The Examiner suggests that restriction of the present invention into the following groups is required:

Group I, claims 1-21, 53-56, 69-89 and 121-124, drawn to devices comprising analyte-specific compound that produces a detectable compound in combination with a substrate;

Group II, claims 22-31, 39-40, 57-58, 90-99, 107-108 and 125-126, drawn to devices comprising analyte-specific compound that chemically couples to analyte;

Group III, claims 32-34, 41-42, 59-60, 100-102, 109-110, 127-128, drawn to devices comprising analyte-specific compound conjugated to an enzyme;

Group IV, claims 35-37, 43-44, 61-62, 103-105, 111-112, and 129-130, drawn to devices, comprising non-analyte specific compound;

Group V, claims 38, 45-48, 63-64, 106, 113-114 and 131-132, drawn to devices comprising a tracer;

Group VI, claims 47 and 115, drawn to methods comprising the step of producing a detectable compound by exposing an analyte-specific compound to an analyte;

Attorney Docket No.: **06244-0002 (CHM-0003)**
Inventors: **Hulkower et al.**
Serial No.: **10/775,780**
Filing Date: **February 10, 2004**
Page 8

Group VII, claims 48 and 116, drawn to methods comprising the step of producing a detectable compound by exposing an analyte-specific compound to an analyte.

Group VIII, claims 49-50, 65-66, 117-118, 133-134, drawn to methods comprising the step of exposing an analyte to a conjugate comprising an analyte-specific compound conjugated to an enzyme; and

Group IX, claims 51-52, 67-68, 119-120, 135-136, drawn to methods comprising the step of exposing an analyte-specific compound to a conjugate comprising an enzyme and a non-analyte specific compound.

The Examiner suggests that the inventions listed as Groups I-IX are independent and distinct from each other. It is suggested that each of the invention groups I-V, and likewise VI-IX, are independent and patentably distinct from each other as they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. The Examiner has acknowledged that inventions (I, II, III, IV or V) and (VI, VII, VIII or IX) are related as product and processes of use; however, the products can be used in materially different processes. Applicants are required to elect one of the Groups to be examined. Further, upon election of a group, the Applicants are required to select one analyte-specific compound, two dyes, and one porphyrin dye from claims reciting multiple species. Applicants respectfully request reconsideration of this restriction requirement.

The present invention relates to an assay for detecting an analyte. The basic assay comprises contacting an analyte with an analyte-specific compound such that upon binding of the analyte

Attorney Docket No.: **06244-0002 (CHM-0003)**
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Serial No.: **10/775,780**
Filing Date: **February 10, 2004**
Page 9

with the analyte-specific compound a detectable compound is produced, wherein the binding of the detectable compound to at least one porphyrin dye produces a detectable response. Therefore, upon review of the restriction requirement and pending claims, Applicants appreciated the necessity of clarifying the present invention. Accordingly, Applicants are canceling claims 1-136 and presenting new claims 137-153 for prosecution. Support for new claims 137-153 can be found in the specification, the original claims, and Figures 1-6, which teach the various embodiments of the claimed assay and kits comprising the same.

As set forth in new claim 137 (also method claim 143 and kit claim 148) and depicted in Figure 1, an analyte (e.g., a substrate such as urea) can be bound by its cognate analyte-specific compound (e.g., enzyme such as urease) to produce a detectable compound (e.g., ammonia) which can be bound by a porphyrin dye to produce a detectable response (e.g., a color change). Embodiments of this assay include the use of an enzyme conjugate (e.g., and antibody-urease conjugate) and enzyme substrate (e.g., urea) as set forth in claim 138 (also method claim 144 and kit claim 149) and depicted in Figure 2B; the use of a non-analyte specific compound (e.g., a first antibody), an enzyme conjugate (e.g., a second antibody conjugated to an enzyme) and enzyme substrate as set forth in claim 139 (also method claim 145 and kit claim 150) and depicted in Figure 3B; and the use of a capture analyte-specific compound (e.g., a third antibody) as set forth in claims 140-141 (also method claim 146 and kit claims 151-152) and depicted in Figure 2A and 3A. However, in each embodiment of the assay, the salient input (i.e., analyte and analyte-specific compound) and output features

Attorney Docket No.: **06244-0002 (CHM-0003)**
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Serial No.: **10/775,780**
Filing Date: **February 10, 2004**
Page 10

(i.e., detectable compound which can be bound by a porphyrin dye to produce a detectable response) are based on the same concept.

As set forth in claim 142 (also method claim 147 and kit claim 153) and depicted in Figure 4, an analyte in a sample can be quantified in a competitive binding assay between the analyte in the sample and a tracer comprising an analyte molecule bound to an enzyme. Once the receptor is bound by either the tracer or analyte, a substrate to the tracer enzyme is added so that a detectable compound is generated, wherein the detectable compound is bound by a porphyrin dye to produce a detectable response.

In view of these amendments, the subject matter of groups III and IV are now presented in claim 137-141; group V in claim 142; and groups VI, VIII and IX in claims 143-146. New claim 147 is a method of use for the device of claim 142. As claims 137-141 and claims 148-152 are related to claims 143-146 as product and process of use, a search of the relevant prior art pertaining to devices comprising an analyte-specific compound that binds to a select analyte so that a detectable compound is produced; and at least one porphyrin dye which binds the detectable compound thereby producing a detectable response would reveal art related to methods for using the same to detect an analyte. Therefore, no additional burden would be incurred by the inclusion of all groups of claims in this application.

However, in an earnest effort to be completely responsive, Applicants hereby elect to prosecute the subject matter presented in new claims 137-141, drawn to a device comprising an analyte-

Attorney Docket No.: **06244-0002 (CHM-0003)**
Inventors: **Hulkower et al.**
Serial No.: **10/775,780**
Filing Date: **February 10, 2004**
Page 11

specific compound and at least one porphyrin dye, classified in class 435, with traverse.

Respectfully submitted,



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